UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	**December 16, 2008**
LISZIEWICZ, et al.	:	**Atty Docket No. RGT 9771**
Serial No. 10/081,922	:	**Group 1632**
Filed: 15 September 1998	:	**Examiner: Wilson**

For: Method of Delivering Genes into Antigen Presenting Cells of the Skin

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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BRIEF ON APPEAL[1]

Following a Notice of Appeal filed October 16, 2008 together with a petition for a three-month extension of time, kindly enter the enclosed Brief of record. A credit card form for the fee set forth in § 41.20(b)2 is enclosed. The Commissioner is authorised to charge any additional fees due, or credit any overage, to Deposit Account No. 50-0855.

The applicant remains entitled to the previously-claimed small entity status.

Respectfully Submitted,

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[1] This paper is being forwarded by fax to the Commissioner of Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on December 16, 2008. Signed Valerie E. Looper

REAL PARTY IN INTEREST

The real party in interest in this case is Genetic Immunity, Inc., a Delaware corporation having an office at 8300 Greensboro Drive, McLean Virginia 22102.

RELATED CASES

As of December 16, 2008, there are no appeals and interferences related to this case. A Notice of Appeal was previously filed in this case Nov. 6, 2006, and an Appeal Brief was filed 5 January, 2007. Prosecution was re-opened by action of the Examiner July 12, 2007. This case is a Division of USPN 6,420,176, which relates to a novel composition of matter. A provisional double-patenting rejection has been made of the inventors' USSN 08/803,484, which relates to a new use for a known class of DNA.

JURISDICTION

This is an appeal under 35 USC 134(a) from a Final Rejection bearing a mail date of April 16, 2008 and setting a shortened 3-month statutory period for reply. A Notice of Appeal together with a petition for a 3-month extension of time and the applicable fee was filed October 16, 2008. Under B. R. 41.37, the due date for this brief is December 16, 2008.

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TABLE OF AUTHORITIES

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STATUS OF AMENDMENTS

No amendment has been filed after the final rejection. The last paper on behalf of the Applicants was filed December 12, 2007.

GROUNDS OF REJECTION

I. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para., New matter, "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives."

II. Objection to Claim 30 under 35 USC § 112, 2nd para., molar ratio

III. Rejection of Claims 23-26, 28, 30-32, 35 and 40, 41 and 43-44 under 35 USC 102(e) as being anticipated under Behr (USPN 6,013,240, Jan 11, 2000; 102(e) date=2-28-97) as supported by Liu (Vaccine, 2002, Vol. 20, pg

42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9).

IV. Rejection of Claims 23-26, 28, 30-32, 35, 40, 41, 43 and 44 under 35 USC 103(a) for obviousness over Behr (US Patent 6,013,240, Jan. 11, 2000) as supported by Liu (Vaccine, 2002, Vol. 20, pg 42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9) and in view of Holler (US Patent 5,908,923).

V. Claims 23-26, 28, 30-33, 35 and 40-43 remain and claim 44 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-71 of copending Application No. 08/803484 in view of the disclosure of '484.

VI. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para, New matter, "without the use of a needle."

STATEMENT OF FACTS

Introduction

The presently claimed invention relates to a new method of administering a vaccine that does not require use of a needle. (App, p. 25, lines 12-13) It has the advantages of being simple, inexpensive (line 15), applicable to a broad range of diseases (lines 17-21), and painless (lines 24-25). In a key experiment (Example 8), DNA complexed with various materials was applied to the prepared skin on the backs of mice for one hour or subcutaneously, and the results were shown in Table 2 (page 23). In Experiment No. 5 of Example 8, DNA formulated in glucose solution and administered transcutaneously performed sixteen times better than the same formulation administered by subcutaneous injection.

I. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para., New matter, "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives."

The Examiner has objected that the language in Claim 23 "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives," is new matter. In a Preliminary Amendment for this divisional application filed February 21, 2002, the Applicants pointed out that Claims 23-41 corresponded to the original Class II of the parent application USSN 09/153,1578. And indeed, in an

Amendment filed June 7, 2004 at page 6, the applicants pointed out specifically that the Examiner quoted original Claim 8 as including the following language: "wherein the complex is selected from the group consisting of DNA conjugates of sugars, polyethylenimine, polyethylenimine derivatives, and mixtures thereof." Further, the Applicants pointed out Examples 6, 7 and 10 in the parent patent, that include a variety of combinations, including DNA, DNA with PEI, DNA and PEI derivatives (-mannose, -galactose and -glucose), some in saline and some in glucose solution. Applicants now point out that DNA and a sugar, DNA and PEI, and DNA and a PEI-derivative (PEI-man) are all found in Table 2, because all were formulated in a sugar solution (page 22, line 35).

II. Objection to Claim 30 under 35 USC § 112, 2nd para., molar ratio

Claim 30 "The method of Claim 26, wherein the complex comprises a 5:1 ratio of mannosylated polyethylenimine nitrogen per DNA phosphate," has been objected to for lack of clarity. Support for this Claim is found at page 22 of the application, lines 9-16, where, to form a neutral complex, the ratio of PEI-man to DNA is 5:1 (lines 11-12). A different ratio applies if the complex is PEI-DNA. Then the ratio of PEI to DNA is 3:1 (line 12).

At item II, page 5 of an office action dated April 16, 2008, the Examiner has objected that mannosylated polyethylenimine nitrogen is not distinguished

from polyethylenimine nitrogen and that Claim 30 does not clearly limit the complex to having mannosylated polythylenimine, and does not further limit Claim 26.

III. Rejection of Claims 23-26, 28, 30-32, 35 and 40, 41 and 43-44 under 35 USC 102(e) as being anticipated under Behr (USPN 6,013,240, Jan 11, 2000; 102(e) date=2-28-97) as supported by Liu (Vaccine, 2002, Vol. 20, pg 42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9).

A. Contents of the File Wrapper

This is a new rejection. The original anticipation rejection over Behr in an office action dated March 10, 2004, starting at page 16. In an amendment filed June 24, 2004, the applicants amended the Claims to recite all the limitations of the single claim not subject to the rejection, and the rejection was not withdrawn. Instead, the Carson reference was added to the rejection in an office action dated Sept. 22, 2004, starting at page 23, and stated that the phrase "A method of transfecting antigen presenting cells" was not being given patentable weight because *it may not occur* (emphasis added) at page 24, lines 2-3.

The rejection for anticipation by Behr as supported by Carson, Mittal and Kuby has been withdrawn after the applicants pointed out in a paper filed